

AMENDMENT TO THE DRAWINGS:

The Examiner requested new corrected drawings in compliance with 37 CFR 1.121(d). The Applicant has prepared new drawings, attached hereto, no new matter is added.

REMARKS/ARGUMENTS

Claims 1 through 8, 10, 12, and 14 through 17 remain in this application.

Claims 9, 11 and 13 have been cancelled.

Claim 1 through 6 and 14 through 17 have been withdrawn as the result of an earlier restriction requirement.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 1 through 6 and 14 through 17 in a divisional application.

Formal drawings are attached hereto, no new matter was added.

In response to the Office Action of **October 23, 2008**, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Rejections under 35 USC 112

Claim 13 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "orthopedic system" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 has been cancelled.

Rejection under 35 USC 103(a)

Claims 7-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over "Artificial Muscles" to Ashley (cited in IDS filed 26 November 2003; hereinafter "Ashley") in view of US 2004/0186576 to Biscup et al. (hereinafter "Biscup").

The Examiner states that Biscup suggests an orthopedic system that includes an expansion mechanism that has electrodes (260 and 262) and an expandable material in order to implant the system in a more compact shape then expand the system once in the body. Biscup does not specifically disclose the transducer structure or an electroactive polymer.

Ashley discloses a transducer that is an electroactive polymer sandwiched between electrodes (see section "How electricity makes a plastic expand) and suggests the transducer be used in medical products (see pg. 54, 1st j). The Examiner states that the transducer of Ashley is used as an expansion mechanism. It would have been obvious to someone of ordinary skill in the art at the time of the invention to use the device of Ashley in the orthopedic system of Biscup, because the substitution of one known expansion system for another would have yielded predictable results, namely to expand the implant. Alternatively, it would have been obvious to use a electroactive polymer as the expandable material in the invention of Biscup, in view of Ashley, since it has been held to

be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

The Examiner states that using a cannula and guide wire in an orthopedic system are well known and are admitted prior art by applicant and would have been obvious to use in the modified system of Biscup, in view of Ashley.

In addition, the Examiner states that with regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the modified device of Biscup, in view of Ashley, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The Applicant has carefully reviewed the prior art. While the Applicant's present invention is directed to a surgical instrument that is capable of producing a cavity within a bone structure; it must be noted that once the cavity has been created the instrument is reduced back to its original size and shape and is removed from the patient, or optional it may remain in the cavity if further use

may be required. The instrument includes an electroactive polymer that has a first state of sufficiently small enough size and shape to fit between the vertebrae and when the electroactive polymer is electrically energized it transforms into a second state. The size and shape of the second state is such that it results in the deformation of the cancellous bone being compressed or tamped and forming a cavity within the cortical bone.

The Ashley article discloses a transducer that is an electroactive polymer and suggests that the transducer has application as a "medical product". An artificial muscle is given as a particular example. Applicant's device is directed to a void creation device which can be precisely manipulated to create a precise void when used in conjunction with MRI or other imaging systems. Applicant's device will also assume its original configuration in the absence of the electrical connection. Ashley does not disclose or suggest such a device.

The Biscup et al patent is directed to an implant for forming a support structure between adjoining vertebrae. The prosthetic implant includes a generally spherical or ellipsoidal body that at least partially engages a surface of adjacent vertebrae. The embodiment shown in Figure 16 has been cited in the prior Office Action. Figure 16 discloses a prosthetic implant 230 that includes a spherical body 240 formed of two semi-hemispherical sections 242

and 244. The prosthetic implant 230 also includes an expandable stabilizer 250. Connected to the stabilizer are two electrodes 260 and 262. The electrodes are designed to direct current to the stabilizer. The stabilizer is formed of a material that will expand when exposed to an electrical current. After the stabilizer 250A has expanded to a desired shape and/or size the expanded stabilizer can be hardened, if desired, by allowing the materials in the stabilizer to natural harden and/or induce hardening by the use of heat, electric current, electromagnetic waves, sound waves, magnetic waves and/or chemical reaction. The Biscup device is drawn to an implant that at least partially engages a surface of adjacent vertebrae whereas applicant's device, as now claimed, is drawn to a void creation device that has a first state which is smaller in size and or shape than the second state. The first state allowing insertion of the device between vertebrae and the second state causing bone compression thereby forming a void between the vertebrae. The transition between the first and second state is achieved by application of electrical energy to the electroactive polymer. The transformation is then reversed, namely from the second state to the first state, upon disconnection of the electrical power source. Applicant's device will not form a support structure between adjacent vertebrae, as per the teachings of Biscup et al, in the absence of electrical energy. The Biscup et

al patent lacks any teaching that describes or suggests the structure or function of applicant's void creating device.

It is well established that in order to establish a proper *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Second there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not base on applicant's disclosure *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2143-\$2143.03.

In light of the above remarks, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness and further contend that a person of ordinary skill in the art, having the references to Ashley and Biscup et al, in front of him or her would not have the information and motivation necessary to arrive at Applicants' invention.

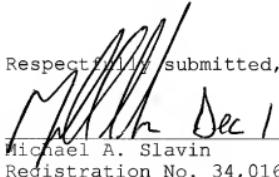
Accordingly, Applicants respectfully submit that the claimed invention distinguishes over the prior art and respectfully request that the rejections of claims 7, 8, 10, and 12 under 35 U.S.C. 103(a) now be withdrawn.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested. Should there be any remaining issues which can be resolved via an Examiner's Amendment; the Examiner is urged to call the undersigned in order to expedite the prosecution of this application.

The Commissioner for Patents is hereby authorized to charge any deficiency in any fees due or credit any overpayments in any fees paid on the filing to Deposit Account No. 13-0439.

Respectfully submitted,


Michael A. Slavin

Registration No. 34,016

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)